CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-251

ENVIRONMENTAL ASSESSMENT and/or FONSI

ENVIRONMENTAL ASSESSMENT

AND

FINDING OF NO SIGNIFICANT IMPACT

FOR

Infasurf™
(Calf Lung Surfactant Extract)
(no USAN name assigned)
Sterile Suspension

NDA 20-521

Ony Inc.

FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

DIVISION OF PULMONARY DRUG PRODUCTS
(HFD-570)

FINDING OF NO SIGNIFICANT IMPACT

NDA 20-521

Infasurf™

(No USAN Name assigned)

Sterile Suspension

The National Environmental Policy Act of 1969 (NEPA) requires all Federal Agencies to assess the environmental impact of their actions. FDA is required under NEPA to consider the environmental impact of approving certain drug product applications as an integral part of its regulatory process.

The Food and Drug Administration, Center for Drug Evaluation and Research, has carefully considered the potential environmental impact of this action and has concluded that it will not have a significant effect on the quality of the human environment and that an environmental impact statement therefore will not be prepared.

In support of their new drug application for Infasurf™, Ony Inc. has prepared an environmental assessment (attached) in accordance with [21 CFR 25.31a(a), which evaluates the potential environmental impacts of the manufacture, use and disposal of the product. The maximum expected environmental concentration is at a level that normally relieves the applicant from completing format items 7, 8, 9, 10, 11, and 15 in accordance with the Tier 0 approach specified in the *Guidance for Industry for the submission of an Environmental Assessment in Human Drug Applications and Supplements*.

Infasurf™ is a natural pulmonary surfactant obtained by extraction of porcine lung tissue. It is administered as a sterile suspension intratracheally in the treatment of neonatal respiratory distress syndrome (RDS) . Both the drug substance and drug product will be manufactured by Ony Inc., Baird Research Park, New York University at Buffalo, Amherst, New York. The finished drug product will be used primarily in hospitals and clinics where premature infants are treated.

Infasurf™ may enter the environment from excretion by patients, from disposal of pharmaceutical waste and from emissions from manufacturing sites.

Disposal of the drug may result from out of specification lots, discarding of unused or expired product, and user disposal of empty or partly used product and packaging. At U.S. hospitals and

clinics, empty or partially empty packages will be disposed according to hospital/clinic regulations.

The Center for Drug Evaluation and Research has concluded that the product can be manufactured, used and disposed of without any expected adverse environmental effects. Precautions taken at the sites of manufacture of the bulk product and its final formulation are expected to minimize occupational exposures and environmental release. Adverse effects are not anticipated upon endangered or threatened species or upon property listed in or eligible for listing in the National Register of Historic Places.

2/6/97
Date

PREPARED BY
Carl J. Berninger, Ph.D.
Environmental Scientist
Environmental Assessment Team
Center for Drug Evaluation and Research

2/6/97
Date

CONCURRED
Nancy B. Sager
Team Leader
Environmental Assessment Team
Center for Drug Evaluation and Research

Attachments: Environmental Assessment (FOI copy)
Material Safety Data Sheet (drug substance)

Copies:

HFD-570

Betty Kuzmik, CSO/PM
Original to NDA 20-521, through Betty Kuzmik, CSO/PM
Division File for NDA 20-521

HFD-205

FOI Copy

HFD-357

EA File for NDA 20-521
Docket File
C. Berninger

File Name: c:\fonsi\20521e01.fcb

APPEARS THIS WAY
ON ORIGINAL

FOI EA
NOA 20-521

1.0 DATE

Original Submission: August 1995

Amended Submission: October 1996

2.0 NAME OF APPLICANT/PETITIONER

ONY Inc.

3.0 ADDRESS

Baird Research Park
1576 Sweet Home Road
Amherst, New York 14228

Town: Amherst

County: Erie

State: New York

Contact Person: William Ferguson
Director of Operations
(716)636-9096

4.0 DESCRIPTION OF PROPOSED ACTION

The intent of this report is to provide sufficient information as specified in the Codes of Federal Regulations, Food and Drugs, 21 CFR Part 25.31 and consistent with 40 CFR Part 1500.4(J) and 1502.21.

4.1 REQUESTED APPROVAL

Infasurf®, a human drug product, is a sterile, non-pyrogenic pulmonary surfactant intended for intratracheal administration only. Infasurf® has been researched and clinically tested for several years for both the prevention (prophylaxis) and the treatment (rescue) of neonatal respiratory distress. ONY Inc. is requesting the approval to manufacture, package, and distribute Infasurf® out of their facility in Amherst, New York.

4.2 NEED FOR THE ACTION

Prevention studies include premature infants less than 33 weeks gestation and treatment studies include all premature infants with established respiratory distress syndrome, RDS, (confirmed by clinical and radiologic findings) requiring mechanical ventilation. Infasurf® (calf lung surfactant extract), when instilled intratracheally into the lungs of premature, surfactant deficient infants before or near the onset of breathing reduces the incidence and severity of respiratory distress syndrome and improves lung function.

The estimated number of pediatric cases, who would annually benefit from Infasurf®, are 100,000 - 120,000 throughout the United States. There is no higher use of surfactant associated with geographical locations. At the successful completion of the clinical trial period, submission of a New Drug Application will be filed with this Confidential Environmental Assessment. ONY Inc. is the developer of Infasurf®, and is proposing its production at the existing facility where the product was developed. It is requested that approval be given, by the FDA, for the use of this drug in an environmentally sound, economically reasonable, and socially acceptable manner.

4.3 LOCATION WHERE THE PRODUCTS WILL BE PRODUCED

The production facility, ONY Inc., for Infasurf® is located at Baird Research Park, of New York State University at Buffalo, Town of Amherst, Erie County, New York.

4.4 LOCATION WHERE THE PRODUCTS WILL BE USED AND DISPOSED OF

The finished product will be used throughout the United States and is not limited to a certain geographical region of the country. However, the ultimate use of the product will be in hospitals for the prevention (prophylaxis) and the treatment (rescue) of neonatal respiratory distress.

This substance has been researched and clinically tested for several years. A review of the study performed as part of a clinical trial period indicated that the amount of waste expected to enter the environment was minimal and, due to its non-toxic characteristics, was not considered a threat to the environment.

Disposal of the product may be needed due to manufacturing activities in the form of discarded out of specification lots, from the discarding of returned and rejected goods or from end users. The physical and chemical characteristics of Infasurf® does not require a controlled method of disposal of the waste generated. Therefore, upon the need for disposal or termination of the drug, or individual unit of empty or partially empty finished product, the liquid residue, which is supplied in glass vials, can be discharged into a sink which is connected to a sanitary sewer. The glass vial may then be discarded into a secured container to maximize the safety related to glass handling, and treated in a similar manner as regular solid waste.

4.5 TYPES OF ENVIRONMENTS PRESENT AT AND ADJACENT TO PRODUCTION LOCATIONS

Baird Research Park is located in an industrially zoned district, with the surrounding area being relatively flat and the climate cold and snowy in the winter and moderately warm in the summer. Current facilities located at the Park consist of various research and development laboratories, commercial and industrial oriented services. Synthesis of the chemical and its incorporation into the product will take place at the only existing designated facility of ONY Inc. located at Baird Research Park, 1576 Sweet Home Road, Amherst, New York.

5.0 IDENTIFICATION OF CHEMICAL SUBSTANCES THAT ARE THE SUBJECT OF THE PROPOSED ACTION

Infasurf® is a sterile, non-pyrogenic pulmonary surfactant. It is an organic solvent extract of calf lung lavage suspended in 0.9% saline for irrigation. This pharmaceutical compound is formulated in the production section of ONY, after having been thoroughly researched by the Research and Development (R&D) section.

The raw materials used in the manufacturing of this drug product in the production facility, includes the calf lung, the whole lung surfactant suspension recovered by 0.9% saline lavage of the organ, the whole lung surfactant pellets produced by centrifuging the lung lavage suspension, 0.9% sodium chloride irrigation, USP, sterile water for irrigation, USP, solvents for extraction of the surfactant pellets and nitrogen used during rotoevaporation in the resuspension process. The following section provides a description of the materials used in the formulation of the drug substance (calf lung surfactant extract - CLSE) and drug product (Infasurf®).

5.1 NOMENCLATURE

Chemical Name:	**Sodium Chloride**
CAS Reg. #:	7647-14-5
Molecular Weight:	58.44
Molecular Formula:	NaCl
Physical Phase:	Granular
Additives:	Purified Water, USP
Impurities:	None

Chemical Name:	**Chloroform**
CAS Reg. #:	67-66-3
Molecular Weight:	119.38
Molecular Formula:	$CHCl_3$
Physical Phase:	Liquid
Additives:	None
Impurities:	None

Chemical Name:	**Methanol**
CAS Reg. #:	67-56-1
Molecular Weight:	32.04
Molecular Formula:	CH_3OH
Physical Phase:	Liquid
Additives:	None
Impurities:	None

Chemical Name:	**Purified Water, USP**
CAS Reg. #:	7732-18-5
Molecular Weight:	18
Structural Formula:	H_2O
Physical Phase:	Liquid
Additives:	None
Impurities:	None

Additional Chemicals:	0.9% Sodium Chloride irrigation, USP Sterile Water for irrigation, USP Nitrogen, NF

CLSE (Drug Substance) is made from calf lung, purified water, sodium chloride granular, USP, methanol, chloroform, 0.9% sodium chloride irrigation, USP, and sterile water for irrigation, USP. CLSE is the lipid and protein moieties of natural lung surfactant dissolved in chloroform (NF). This complex biologic material is 90-95% phospholipid, 5-7% cholesterol, and 1-3% hydrophobic surfactant specific proteins (SP-B, SP-C). The presence and quantification of other possible trace (<1%) neutral lipid materials in CLSE is not available.

Infasurf® contains CLSE, 0.9% sodium chloride irrigation, USP, sterile water for irrigation, USP, and trace amounts (≤ 10 ppm) of chloroform and (≤ 200 ppm) methanol. Information concerning the molecular weight and structural formula for calf lung surfactant extract is unknown as it is a complex biologic material. Therefore, the previous format used for the identification of the chemical substances can not be used in the identification of the aforementioned components.

Note: **Appendix A contains confidential information concerning the composition of Infasurf®.**

Appendix B contains the Material Safety Data Sheet (MSDS).

6.0 INTRODUCTION OF SUBSTANCES INTO THE ENVIRONMENT

The central question in an assessment of environmental impact is: What effects will the proposed action have on the environment of the area affected by the action? More important, are any of these predicted effects adverse, or could they be cause for concern? (Usually, the term environmental impact is reserved for those effects considered significant, especially when they are undesirable or potentially adverse, or those that call for a mitigation or intervention of some kind.)

This section addresses the questions and concerns raised by the introduction of substance into the environment. Its scope is the result of several influences: United States Environmental Protection Agency (USEPA), New York State Department of Environmental Conservation (NYSDEC) regulations and recommendations, local agencies, research findings, and the experience of consultants, with similar projects.

The basis for organizing the study and for presenting the results is a list of environmental issues or "parameters" judged relevant to the current project. A convenient way to classify these issues is in three broad categories: effects on the physical environment; effects on the biological environment; and effects on the socio-economic environment.

RESEARCH & DEVELOPMENT

The Research & Development section of ONY Inc., uses a large number of chemicals in small quantities. The materials in use at any given time will vary depending upon the focus of the Research & Development program. Chlorinated and non-chlorinated solvents such as chloroform and methanol are commonly used for extraction and analysis. Acetic Acid is the most widely used acid.

Research and development in the pharmaceutical industry encompasses several fields, including chemical, microbiological, and pharmacological research.

The R&D section is divided into two groups, the Synthetic Chemistry Division and the Product Development Division.

PRODUCTION

Infasurf® is produced in batches where the raw materials are used to extract the drug substance from a biological organ. This pharmaceutical compound is

formulated in the production section of ONY, after having been thoroughly researched by the Research and Development (R&D) section. The finished products are sampled and analyzed by ONY (in house) and independent (outside contractor) laboratories. The analysis results are then provided to a QA group for final review and authorization for use. As a result of this stringent implementation of QA/QC programs, during the formulation stage the possibility of reject products has been minimized (three lots since 1987).

PACKAGING

After satisfactory analysis results have been obtained, the formulated compounds are released for packaging into the finished product containers where they are again sampled by QA/QC personnel. To date, there has not been any rejected product during the packaging operation.

6.1 & 6.2 LIST OF SUBSTANCES EXPECTED TO BE EMITTED AND CONTROL EQUIPMENT EXERCISED

The ONY Inc. manufacturing facility is constructed and designed to operate in full compliance with current standards and FDA's good laboratory and manufacturing practices.

The principal waste streams generated by the R&D section are spent solvent, spent corrosive, and expired products. The Production section mostly includes equipment and floor cleaning water and rejected products, and the packaging section consists mostly of shipping containers, paper products, and rejected products.

AIR EMISSIONS AND CONTROL EQUIPMENT

The substances released into the atmosphere as a result of the proposed action includes solvents used for extraction processes, primarily chloroform and methanol. Although the air emissions are minimal, and control equipment is not required, for good pharmaceutical practice, an exhaust laboratory fume hood has been employed. The released chemicals are emitted through the stack of the laboratory fume hood which is equipped with an exhaust blower. This practice is in full compliance with occupational health provision, safety and environmental control regulations of OSHA.

The heating, ventilation, and air-conditioning system is monitored and controlled. The air quality within the facility is maintained by high efficiency particulate absorption (HEPA) filtration. The HEPA filters are protected by pre-filters and

particle counts and velocity are monitored to ensure effectiveness.

LIQUID WASTE STREAM AND CONTROL EQUIPMENT

The liquid waste stream is divided into two categories as follows:

a. Regulated liquid waste and control equipment
b. Non-regulated liquid waste and control equipment

a. REGULATED LIQUID WASTE AND CONTROL EQUIPMENT

The principal waste streams generated at the site include spent solvents, such as methanol and chloroform used for product processing and recovery. After use, they will be collected in waste storage containers, properly labeled and handled as instructed by the USEPA, and NYSDEC. These containers are stored in an area designated for hazardous waste material storage until it is transported by an USEPA and NYSDEC certified hauler and disposed of in a disposal site which is approved by USEPA and NYSDEC.

b. NON-REGULATED LIQUID WASTE AND CONTROL EQUIPMENT

The liquid waste released due to the proposed action will have low to medium biochemical oxygen demand (BOD), chemical oxygen demand (COD), total suspended solids (TSS) and total dissolved solids (TDS) concentration, and are classified as water soluble and non-hazardous material. Physical and chemical characteristics of the drug product does not restrict its discharge into the waste water treatment plant as it is a non-hazardous biologic (municipal sanitary sewer). The final concentration reaching the sewer or the aquatic environment would be undetectable and insignificant. Sanitary waste from toilets, sinks, and non process areas are also discharged directly into the sanitary sewer. All other processes within the building are monitored and discharged into an on-site acid neutralization tank for pH balance. The neutralization tank will then adjust the pH and discharge the waste into a holding tank prior to final discharge to the municipal sanitary sewer.

SOLID WASTE AND CONTROL EQUIPMENT

The non-hazardous solid waste generated at the site includes calf lung, glass vials, laboratory waste and ordinary office and sanitary waste, which will be removed and carted to the landfill. Empty vials and shipping containers generated at the medical facilities where the product is used will be discarded in accordance with local disposal codes and regulations. Since the waste is not considered to be hazardous it will be deposited into designated trash bins for proper disposal. Disposal of production and used debris will be controlled by applicable solid waste regulations imposed at the disposal site.

6.3 CITATION OF AND STATEMENT OF COMPLIANCE WITH APPLICABLE EMISSIONS LEVEL

a. AIR EMISSIONS

Under section 114 of the Act (42 U.S.C.7414), U.S. Environmental Protection Agency has been given the broad authority to evaluate the compliance status of emissions released by any source of pollutant. Subsequent to this Act, NYSDEC has been designated as the regulatory representative of the USEPA.

A recent evaluation of the released material was performed and reported to NYSDEC for an Air Pollution Process Permit. The results indicated that the emitted substances are far below the emission standards and incompliance with the Clean Air Act regulations of NYSDEC, 6NYCRR Part 212.

b. REGULATED WASTE

A permit application for Notification of Regulated Waste Activity has been filed with and approved by the USEPA indicating compliance with Section 3010 of the Resource Conservation and Recovery Act (RCRA), found in the Codes of Federal Regulations (CFR) Title 40, Part 261, Hazardous Waste Regulations.

c. LIQUID WASTE

The amount of waste water released to the sanitary sewer at the production site, due to the proposed action, will not require a discharge permit from the Amherst Metropolitan Sewer District. However, as per the requirements of 40 CFR Part 403.8, for Publicly Owned

Treatment Works (POTW), spot sampling and a review of the operational processes will be performed during the fiscal year by authorities of the sewer district to assure compliance, and/or inform the facility operator of the favorable nutrient for the central treatment facility. A recent sampling of the released material was performed by the Amherst Metropolitan Sewer District through and their investigation indicated compliance and an acceptable operation.

d. NON-REGULATED WASTE

As per NYSDEC Division of Hazardous Waste Material, the fresh calf lung with 0.9% NaCl is not considered a regulated waste, and it does not require any environmental permit, special attention and/or handling. However, all solid disposal methods are conducted in accordance with the solid waste disposal regulations of the State of New York, Erie County.

6.4 THE EFFECT OF THE APPROVAL OF THE PROPOSED ACTION WILL HAVE UPON COMPLIANCE WITH CURRENT EMISSIONS REQUIREMENTS AT THE PRODUCTION SITE

ONY Inc. is designed to meet all applicable emission requirements. No affect of the proposed action is anticipated for continued compliance with current emission requirements.

AIR EMISSIONS

The approval of the proposed action will not have a significant environmental effect at the production site as documented in the NYSDEC permit application.

NON-REGULATED LIQUID WASTE

A commercial/industrial survey conducted by pretreatment Department of the Town of Amherst Sewer System, revealed that, ONY Inc. is in compliance with General Pretreatment Regulations (40 CFR 403.8 (f) (2) (i)) and is not subject to a any restriction or permit for said operation.

SOLID WASTE

Solid waste generated as a result of ONY Inc. operation at the production site is minimal and has no significant environmental effects.

6.5 QUANTITIES AND CONCENTRATIONS OF SUBSTANCES EXPECTED TO ENTER THE ENVIRONMENT

AIR EMISSIONS

In accordance with the Rules of the New York State Department of Environmental Conservation, a permit application was submitted for Process Exhaust and/or Ventilation Systems. Through material balance calculations it was demonstrated that the processes within this facility are in compliance with all applicable emission standards.

AIR EMISSIONS CALCULATION

Chloroform (CAS # 67-66-3);
Chloroform used per year = 211 gal/yr
80% of the chloroform will be captured and discharged into the waste drum for proper disposal.
Chloroform Emitted = (211 gal/yr) x 1.49 x (8.34 lbs/gal) x 20% Emission Factor = 524.4 lbs/yr

Methanol (CAS # 67-56-1);
Methanol used per year = 213 gal/yr
Methanol Emitted = (213 gal/yr) x 0.79 x (8.34 lbs/gal) x 10% Emission Factor = 140.3 lbs/yr

Misc. organic solvents (CAS # NY990-00-0);
Misc. organic solvent used = 3.5 gal/yr
Misc. organic solvent emitted = (3.5 gal/yr) x 0.78 x (8.34 lbs/yr) x 20% Emission factor = 4.55 lbs/yr

Misc. in-organic solvents (CAS # NY999-00-4);
Misc. in-organic solvent used = 2.5 gal/yr
Misc. in-organic solvent emitted = (2.5 gal/yr) x 0.78 x (8.34 lbs/yr) x 20% Emission factor = 3.25 lbs/yr

NON-REGULATED LIQUID WASTE

The waste water discharge into the sewer system from ONY Inc. is expected to be 800 gallons per day (gpd) from the production facility.

REGULATED WASTE

Total regulated waste (hazardous waste) generated at ONY Inc. is estimated to be 5 - 6 gpd.

Note: This is a maximum amount based on full production 4 days/week

SOLID WASTE

Combined solid waste from production, laboratories, office trash and corrugated containers are expected to be 8 cubic yards per week (320 yards per year).

NON-REGULATED LIQUID WASTE

Following the commercial/industrial survey conducted by the Pretreatment Department of the Town of Amherst Sewer System, a sample of the waste water was collected by the town officials and analyzed. The results of the analysis indicated that ONY Inc. is in compliance with the General Pretreatment Regulations (40 CFR 403.8 (f) (2) (i)) and is not subject to any restrictions or permitting for said operation.

EXPECTED INTRODUCTION CONCENTRATION

The drug substance entering the environment as a result of use and disposal, has been estimated based on total fifth year production forecasts. If the following Expected Introduction Concentration (EIC) calculation is less than 1 ppb, it is unlikely to have a significant effect on the environment. (See Confidential Appendix A for EIC calculations).

Since the EIC was calculated to be 4.8×10^{-4} ppb it is unlikely to have a significant effect on the environment. Therefore, Tier 0 has been met. Appendix A contains confidential information concerning the production estimates of Infasurf® and calculation of the EIC.

09 020

12.0 LIST OF PREPARERS

Forest Laboratories, Inc.
909 Third Avenue
New York, NY 10022-4731

Richard S. Overton	VP Operations and Facilities
Professional Experience:	30 Years, Pharmaceutical Facilities and Operations Management
Marion Ceruzzi, PhD	Assistant Director Regulatory Affairs
Professional Experience:	6 Years, Pharmaceutical R&D 4 Years, Regulatory Affairs

ONY Inc.
Baird Research Park
1576 Sweet Home Road
Amherst, NY 14228

William H. Ferguson	Director of Operation
Professional Experience:	8 Years, Clinical Respiratory Care, CRTT, 5 Years Academic Research Pulmonary Physiology, 6 Years, Director of Production ONY Inc.
Edmund A. Egan M.D.	President, Chief Medical Officer
Professional Experience:	27 Years, Clinical Medicine 21 Years, Academic Medicine and Physiology Faculty, 10 Years, President ONY, Inc.

ESPL Environmental Consultants Corporation
110 Greenwich Street
New York, New York 10006

Ali Gooya, PhD, M.E.	Director Environmental Science
Professional Experience:	8 Years, Engineering & Environmental Science

Ray Kahn, M.S.M.E.	Director Environmental Technologies
Professional Experience:	10 Years, Engineering, Environmental Science & Pollution Control
Sidney Rosen, P.E.	Project Manager
Professional Experience:	40 Years, Engineering Environmental Science & Pollution Control

13.0 CERTIFICATION

"The undersigned official certifies and states that the information presented is true and, accurate, and complete to the best of the knowledge of the firm or agency responsible for preparation of the environmental assessment"

William H. Ferguson	Director of Operations
Print Name	Title
Signature	Date

14.0 REFERENCES

American Chemical Society, Washington D.C., 1990

American Conference of Governmental Industrial Hygienists (ACGIH) Inc.

American Society for Testing and Materials

Documentation of the Threshold Limit Values, Cincinnati, Ohio

Erie County Department of Environmental and Planning

Food & Drugs Administration
- Center for Drugs Evaluation & Research

Forest Laboratories, Inc.

Handbook of Chemical Property Estimation Methods, W.J. Lyman, W.F. Reehl, and D. H. Rosenblatt

Handbook of Environmental Data on Organic Chemicals, Verschureren, Lasala, A.M., Jr., W.E. Harding, and R.J. Archer, 1964

Method for Classification of Soils for Engineering Purposes

Metropolitan Sewer District

New York State Department of Environmental Conservation
- Division of Air, Steven J. Doleskie
- Division of Hazardous Waste Management

New York State Department of Health

ONY Inc.

Pharmaceutical Manufacturing Association, Interim Guidance to the Pharmaceutical Industry for Environmental Assessment Compliance Requirements for the FDA

Sanborn Map Company

"Technical Assistant Document (TAD) 2.00" FDA Environmental Assessment

Technical Assistance Handbook, NTS PB 87-175354

United States Department of Agriculture, Soil Survey of Erie County, New York

United State Department of Commerce, 1974, Census of Agriculture, Bureau of the Census, State and County Data, Vol. 1, pt. 32, sec. IV, 85-90 pp.

U.S. Geological Survey Water Resources Investigation Report 84-4334 / Report 86-4317 / Report 88-4076

United States Environmental Protection Agency, Office of Air Quality Planning and Standards

United States Environmental Protection Agency, Air & Waste Management Division, Hazardous & Solid Waste Program Branch

Water Resources of the Lake Erie-Niagara Area, New York
- a preliminary appraisal, New York Water.

APPENDIX B:

Material Safety Data Sheet

Material Safety Data Sheet ONY, Inc.

Infasurf®

Effective Date: 10/21/96 Supersedes 09/07/93

ONY, Inc.•Baird Research Park•1576 Sweet Home Road•Amherst, New York 14228•Telephone: (716)636-9096•Fax: (716)636-3942

PRODUCT IDENTIFICATION:

Synonyms: calf lung surfactant extract, CLSE, pulmonary surfactant
CAS No.: None
Molecular Weight: Unknown
Chemical Formula: Unknown
Hazardous Ingredients: None

PRODUCT COMPOSITION:

Infasurf® contains natural phospholipids, neutral lipids and hydrophobic surfactant associated proteins suspended in 0.9% sodium chloride.

PRODUCT DESCRIPTION:

Infasurf® (calf lung surfactant extract) Intratracheal Suspension is a sterile, non-pyrogenic lung surfactant intended for intratracheal instillation only. It is an extract of natural surfactant from calf lungs.

Infasurf is an off-white suspension of calf lung surfactant extract (CLSE) in 0.9% sodium chloride solution. Each mL of Infasurf contains: 35 mg total phospholipids (including 19-28 mg/mL phosphatidylcholine & 12-18 mg/mL of dissaturated phosphatidylcholine) and 0.55-0.80 mg/mL surfactant proteins. It is supplied as a 6 mL (210 mg phospholipids) single use vial.

PRECAUTIONARY MEASURES:

- Avoid contact with eyes.

EMERGENCY FIRST AID:

In case of eye contact, immediately flush eyes with plenty of water. Call a physician if irritation occurs. SEE SECTION 5.

Infasurf®

Effective Date: 10/21/96 Supersedes 09/07/93

ONY, Inc.•Baird Research Park•1576 Sweet Home Road•Amherst, New York 14228•Telephone: (716)636-9096•Fax: (716)636-3942

SECTION 1 - Physical Data

Appearance: off-white, unstable aqueous suspension
Odor: no specific odor
Solubility: insoluble in water, very soluble in chloroform and other organic solvents
Boiling Point: ≃ 100°C (approximately that of water)
Melting Point: ≃ 0°C (approximately that of water)
Specific Gravity: 1.08
Vapor Pressure (mm Hg): No information found
Vapor Density (Air=1): No information found
Evaporation Rate: No information found

SECTION 2 - Fire and Explosion Information

Fire:

Not a fire hazard.

Explosion:

Not an explosion hazard.

Fire Extinguishing Media:

Use any means suitable for extinguishing surrounding fire.

SECTION 3 - Reactivity Data

Stability:

Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products:

None. Oxidation products are CO_2 and H_2O

Hazardous Polymerization:

Will not occur.

Incompatibilities:

No information found.

SECTION 4 - Leak/Spill Disposal Information

Spills: Wipe or mop up and container for disposal. Disposal: Contains no hazardous materials. May be disposed of as normal, non-hazardous solid or liquid waste.

Dispose of container and unused contents in accordance with federal, state and local requirements.

ONY, Inc.•Baird Research Park•1576 Sweet Home Road•Amherst, New York 14228•Telephone: (716)636-9096•Fax: (716)636-3942

SECTION 5 - Health Hazard Information

A. Exposure/Health Effects

Inhalation:
None known.

Ingestion:
None known.

Skin Contact:
Not expected to be a health hazard.

Eye Contact:
May cause irritation.

Chronic Exposure:
No information found.

Aggravation of Pre-existing Conditions:
No information found.

B. First Aid

Inhalation:
Get medical attention for any breathing difficulty.

Ingestion:
If large amounts were swallowed, get medical advice.

Skin Exposure:
Wash exposed area with soap and water. Get medical advice if irritation develops.

Eye Exposure:
Wash thoroughly with running water. Get medical advice if irritation develops.

C. Toxicity

None known.

SECTION 6 - Occupational Control Measures

None established.

SECTION 7 - Storage and Special Information

Keep in the container/closure supplied until use, refrigerate at 2-8°C. Protect against light and physical image.

General Healthcare Division

Baxter Healthcare Corporation
One Parkway North, Suite 100
Post Office Box 851
Deerfield, Illinois 60015-0851

708 940 1[illegible]
Fax 708 94[illegible]935

Baxter

June, 1992

Dear Valued Customer:

This letter is in response to your recent request for Material Safety Data Sheets (MSDS) on one or more of the following Baxter Products:

0.9% Sodium Chloride Irrigation, USP
0.9% Sodium Chloride Injection, USP
0.9% Sodium Chloride Inhalation, USP
0.45% Sodium Chloride Injection, USP
0.45% Sodium Chloride Inhalation, USP
Sterile Water for Irrigation, USP
Sterile Water for Injection, USP
Sterile Water for Inhalation, USP
5% Dextrose Injection, USP
Plasmalyte® R, A, 56, and 148, Injection
10 % Osmitrol in Water (Mannitol Injection, USP)
Lactated Ringer's Injection, USP
Lactated Ringer's and 5% Dextrose Injection, USP
5% Dextrose and Ringer's Injection
5% Dextrose 0.9% Sodium Chloride Injection, USP
5% Dextrose 0.45% Sodium Chloride Injection, USP
5% Dextrose 0.2% Sodium Chloride Injection, USP
20 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection
10 mEq/L Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection
0.25% Acetic Acid Irrigation, USP
3% Sorbitol Urologic Irrigating Solution
1.5% Glycine Irrigation, USP (Aminoacetic Acid Irrigation)
Bacteriostatic Water for Injection, USP, with Benzyl Alcohol
Bacteriostatic Water for Injection, USP, with Parabens

These solution products are exempt from OSHA Hazard Communication Standards because they contain no hazardous ingredients. The information sent with the product in the form of Package Inserts and/or Product Labeling provides data on ingredients, hazards associated with use, and handling precautions. In most cases, this information is more detailed than required on a Standard Material Safety Data Sheet.

If we may be of further assistance, do not hesitate to contact customer service at (800) 635-6021 or (800) 423-2311.

Sincerely,

Glenn Balasky
Quality Assurance Manager
Baxter General Healthcare Division

American Burdick & Jackson
Material Safety Data Sheet

MATERIAL SAFETY DATA SHEET

CHLOROFORM

8 Liters QC

emergency telephone no. 312/973-3600 (American Scientific Products)
chemtrec telephone no. 800/424-9300
information telephone no. 616/726-3171 (American Burdick & Jackson)

I. Identification

chemical name Chloroform molecular weight 119.38
chemical family Chlorinated Hydrocarbon formula $CHCl_3$
synonyms Trichloromethane
DOT proper shipping name Chloroform
DOT hazard class ORM-A
DOT identification no. UN1888 CAS no. 67-66-3

II. Physical and Chemical Data

boiling point, 760mm Hg. 61.2°C freezing point -63.5°C evaporation rate (ether=1) ca 0.6
vapor pressure at 20°C 159 mm Hg vapor density (air = 1) 4.1 solubility in water @ 20°C 0.8%
% volatiles by volume ca 100 specific gravity (H_2O = 1) @ 20°C 1.49 stability Stable
hazardous polymerization Not expected to occur.
appearance and odor Clear, colorless liquid with a mildly sweet odor.
conditions to avoid Heat, sparks, open flame, open containers, poor ventilation, and moisture.
materials to avoid Active metals and strong alkaline solutions.
hazardous decomposition products Phosgene, hydrogen chloride, and chlorine.

III. Fire and Explosion Hazard Data

flash point, (test method) None (closed cup) auto ignition temperature Not known
flammable limits in air % by volume: lower limit na upper limit na
unusual fire and explosion hazards Concentrated vapors can be ignited by high intensity heat source or flame. Toxic and corrosive gases are formed on contact with flames or hot glowing surfaces.
extinguishing media Non-flammable material. Use dry chemical, carbon dioxide, foam or water spray as appropriate for surrounding fire and materials.
special fire fighting procedures Non-flammable material. Wear full protective clothing and self-contained breathing apparatus. Heat will build pressure and may rupture closed storage containers. Keep fire-exposed containers cool with water spray.

IV. Hazardous Components

	%	TLV	CAS no.
Chloroform plus stabilizer (see supplement)	ca 100	10 ppm	67-66-3

V. Health Hazards

Occupational Exposure Limits

OSHA	8-hour PEL	-	not listed
	Ceiling	-	50 ppm
	Peak	-	not listed
ACGIH	TLV-TWA	-	10 ppm
	TLV-STEL (15-min)	-	50 ppm
NIOSH	TLV-TWA	-	not listed
	TLV-C (1-hour)	-	2 ppm

Concentration Immediately Dangerous to Health

OSHA/NIOSH	1000 ppm

Odor Threshold

OHS	100 ppm
NSC	200 ppm

Carcinogenic, Mutagenic, and Teratogenic Data

Suspected carcinogen in humans (IARC, ACGIH, NTP)
Animal carcinogen (IARC); Animal teratogen (RTEC)
Positive carcinogen in mice (NCI); Positive mutagen (RTEC)

Primary Routes of Entry

Chloroform may exert its effects through inhalation, skin absorption, and ingestion.

Industrial Exposure: Route of Exposure/Signs and Symptoms

Inhalation:	Exposure can cause nausea, vomiting, drowsiness, headache and dizziness, unconsciousness, and even death in extreme cases. Subsequent liver and kidney damage may result from both acute and chronic exposure. Chloroform can cause olfactory fatigue and has poor warning properties.
Eye Contact:	Liquid or high vapor concentration can cause pain and irritation with slight corneal injury possible.
Skin Contact:	Prolonged or repeated skin contact can cause irritation and dermatitis through defatting of skin.
Ingestion:	Swallowing is followed by burning of throat and mouth. Liver and kidney damage can result.

Effects of Overexposure

Acute exposure causes excitation followed by dizziness, nausea, headache, unconsciousness, and respiratory failure. Death may occur from cardiac arrest or hepatic damage. Chronic inhalation may result in liver or kidney damage. High concentrations of vapor cause conjunctivitis and spasmodic winking. Liquid contact with eye results in burning pain and irritation, with possible corneal injury.

Medical Condition Aggravated by Exposure

Preclude from exposure individuals with diseases of liver, kidneys and central nervous system. Simultaneous exposure to chloroform and alcohol can increase the toxic hazards of chloroform.

Emergency First Aid

Inhalation:	Immediately remove to fresh air. If not breathing, administer mouth-to-mouth resuscitation. If there is no pulse, administer cardiopulmonary resuscitation (CPR). Contact physician immediately.
Eye Contact:	Rinse with copious amounts of water for at least 15 minutes. Get emergency medical assistance.
Skin Contact:	Flush thoroughly for at least 15 minutes. Wash affected skin with soap and water. Remove contaminated clothing and shoes. Wash clothing before re-use and discard shoes. Get emergency medical assistance.
Ingestion:	Call local Poison Control Center for assistance. Contact physician immediately. Never induce vomiting or give anything by mouth to a victim unconscious or having convulsions.

Note to Physician

Annual physical exams of exposed persons should make special reference to liver and kidney function.

VI. Safety Measures and Equipment

Ventilation:	Adequate ventilation is required to protect personnel from exposure to chemical vapors exceeding the PEL. The choice of ventilation equipment, either local or general, will depend on conditions of use, quantity of material, and other operating parameters.
Respiratory:	Use approved respirator equipment. Follow NIOSH and equipment manufacturer's recommendations to determine appropriate equipment (air-purifying, air-supplied, or self-contained breathing apparatus).
Eyes:	Safety glasses are considered minimum protection. Goggles or face shield may be necessary depending on quantity of material and conditions of use.
Skin:	Protective gloves and clothing are recommended. The choice of material must be based on chemical resistance and other user requirements. Generally, neoprene or Buna-N offers acceptable chemical resistance. Individuals who are acutely and specifically sensitive to chloroform may require additional protective equipment.

Storage: Chloroform should be protected from moisture, temperature extremes, and direct sunlight. Proper storage of chloroform must be determined based on other materials stored and their hazards and potential chemical incompatibility. In general, chloroform should be stored in a cool, well ventilated and secure toxic storage room.

Other: Emergency eye wash fountains and safety showers should be available in the vicinity of any potential exposure.

VII. Spill and Disposal Data

Spill Control: Wear protective clothing and use approved respirator equipment. Absorb spilled material in an absorbent recommended for solvent spills and remove to a safe location for disposal by approved methods. If released to the environment, comply with all regulatory notification requirements.

Waste Disposal: Dispose of chloroform as an EPA hazardous waste. Hazardous waste number - U044(Toxic).

VIII. Supplement

Hazardous Components

Stabilizer will consist of either:

a) ca 50 ppm amylene

b) ca 1% ethanol + 50 ppm amylene
Ethanol has a TLV of 1000 ppm (ACGIH).
Ethanol is a suspected carcinogen and teratogen (NIOSH).

Revision Date: 1/85

KEY

ca	Approximately	STEL	Short Term Exposure Level
na	Not applicable	TLV	Threshold Limit Value
C	Ceiling	TWA	Time Weighted Average
PEL	Permissable Exposure Level	BuAc	Butyl Acetate

NSC National Safety Council ("Fundamentals of Industrial Hygiene", 1983)
OHS Occupational Health Services ("Hazardline")

Baxter Healthcare Corporation
Burdick & Jackson Division
1953 South Harvey Street
Muskegon, MI 49442 USA

information/emergency telephone no. 616.726.3171
chemtrec telephone no. 800.424.9300
canadian emergency telephone no. 613.996.6666

MATERIAL SAFETY DATA SHEET

METHANOL

I. Identification

chemical name Methanol — molecular weight 32.04
chemical family Alcohol — formula CH_4O
synonyms Carbinol, Methyl Alcohol, Wood Alcohol
DOT proper shipping name Methyl Alcohol or Methanol
DOT hazard class Flammable Liquid
DOT identification no. UN1230 — CAS no. 67-56-1

II. Physical and Chemical Data

boiling point, 760mm Hg. 64.7°C — freezing point -97.7°C — evaporation rate (BuAc=1) ca 5
vapor pressure at 20°C 97 mm Hg — vapor density (air=1) 1.11 — solubility in water @ 20°C complete
% volatiles by volume ca 100 — specific gravity (H_2O=1) @ 20°C 0.792 — stability Stable
hazardous polymerization — Not expected to occur.
appearance and odor A clear, colorless liquid with a slight alcoholic odor.
conditions to avoid Heat, sparks, open flame, open containers, and poor ventilation.

materials to avoid Strong oxidizing agents and reactive metals which will displace hydrogen.

hazardous decomposition products Incomplete combustion can generate carbon monoxide and other toxic vapors such as formaldehyde.

III. Fire and Explosion Hazard Data

flash point, (test method) 12°C (Tag closed cup) — auto ignition temperature 385°C
flammable limits in air % by volume: lower limit 6.7 — upper limit 36.5
unusual fire and explosion hazards May burn with an invisible flame. Mixtures with water as low as 21% by volume are still flammable (flash point below 37.8°C). Under some circumstances can corrode certain metals, including aluminum and zinc, and generate hydrogen gas.
extinguishing media Carbon dioxide, dry chemical, alcohol foam, water mist or fog.

special fire fighting procedures Wear full protective clothing and self-contained breathing apparatus. Heat will build pressure and may rupture closed storage containers. Keep fire-exposed containers cool with water spray.

IV. Hazardous Components

	%	TLV	CAS no.
Methanol	ca 100	200 ppm (skin)	67-56-1

Health Hazards

Occupational Exposure Limits

OSHA	TWA	- 200 ppm
	STEL	- 250 ppm
	Ceiling	- not listed
ACGIH	TLV-TWA	- 200 ppm
	TLV-STEL	- 250 ppm
NIOSH	10 hour TWA	- 200 ppm
	15 min Ceiling	- 800 ppm

Concentration Immediately Dangerous to Health

OSHA/NIOSH	25,000 ppm

Odor Threshold

NSC	10 ppm
NIOSH	2000 ppm

Carcinogenic Data

Methanol is not listed as a carcinogen by IARC, NTP, OSHA, or ACGIH.

Primary Routes of Entry

Methanol may exert its effects through inhalation, skin absorption, and ingestion.

Industrial Exposure: Route of Exposure/Signs and Symptoms

Inhalation: Exposure can cause drowsiness and intoxication, headache, visual disturbance leading to blindness, coughing and shortness of breath, collapse and death at high concentrations.

Eye Contact: Liquid can cause moderate burning, watering, swelling, and redness; high vapor concentration (greater than 2000 ppm) may cause same symptoms.

Skin Contact: This substance may be absorbed through intact skin and produce toxic effects. Extensive, repeated and/or prolonged skin contact can cause burning, itching, redness, or blisters.

Ingestion: Causes burning of the gastrointestinal tract and toxic effects. Swallowing more than 2 ounces of methanol can cause death.

Effects of Overexposure

Mild poisoning is characterized by fatigue, nausea, headache, and delayed visual blurring. Moderate intoxication results in severe depression. Temporary or permanent blindness may follow in 2-6 days. In severe poisoning, symptoms progress to rapid, shallow respiration, cyanosis, coma, hypotension, dilated pupils, and visual disturbance. Death may result from respiratory failure.

Medical Condition Aggravated by Exposure

Preclude from exposure those individuals with diseases of eyes, liver, kidneys, and lungs.

Emergency First Aid

Inhalation: Immediately remove to fresh air. If not breathing, administer mouth-to-mouth rescue breathing. If there is no pulse administer cardiopulmonary resuscitation (CPR). Contact physician immediately.

Eye Contact: Rinse with copious amounts of water for at least 15 minutes. Get emergency medical assistance.

Skin Contact: Flush thoroughly for at least 15 minutes. Wash affected skin with soap and water. Remove contaminated clothing and shoes. Wash clothing before re-use, and discard contaminated shoes. Get emergency medical assistance.

Ingestion: Call local Poison Control Center for assistance. Contact physician immediately. Never induce vomiting or give anything by mouth to a victim unconscious or having convulsions.

Note to Physician

In case of ingestion or massive inhalation, observe victim as an inpatient because slow metabolism causes a latent period of 24 hours between exposure and acidosis and blindness.

Safety Measures and Equipment

Ventilation: Adequate ventilation is required to protect personnel from exposure to chemical vapors exceeding the PEL and to minimize fire hazards. The choice of ventilation equipment, either local or general, will depend on the conditions of use, quantity of material, and other operating parameters.

Respiratory: Use approved respirator equipment. Follow NIOSH and equipment manufacturer's recommendations to determine appropriate equipment (air-purifying, air-supplied, or self-contained breathing apparatus).

Eyes: Safety glasses are considered minimum protection. Goggles or face shield may be necessary depending on quantity of material and conditions of use.

Skin: Protective gloves and clothing are recommended. The choice of material must be based on chemical resistance and other user requirements. Generally, neoprene, nitrile rubber, or rubber offer acceptable chemical resistance. Individuals who are acutely and specifically sensitive to methanol may require additional protective equipment.

MATERIAL SAFETY DATA SHEET

SODIUM CHLORIDE

MALLINCKRODT

Effective Date: 08-08-86 Supersedes 08-07-85

A Division of Mallinckrodt Baker, Inc. • 222 Red School Lane • Phillipsburg NJ 08865 • Telephone: (908) 859-2151 • Fax (908) 859-9318
Emergency Phone: 908-859-2151 • CHEMTREC: 202-483-7616 • CANUTEC: 613-996-6666

PRODUCT IDENTFICATION:

Synonyms: Salt
CAS No.: 7647-14-5
Molecular Weight: 58.44
Chemical Formula: NaCl
Hazardous Ingredients: Sodium chloride

PRECAUTIONARY MEASURES:

WARNING! CAUSES EYE IRRITATION.

- Avoid contact with eyes.
- Wash thoroughly after handling.

EMERGENCY FIRST AID:

In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician. SEE SECTION 5.

SECTION 1 - Physical Data

Appearance: White crystalline.
Odor: Odorless.
Solubility: 36g/100cc water @ 20 C (68 F)
Boiling Point: 1413 C (2575 F)
Melting Point: 801 C (1474 F)
Specific Gravity: 2.16
Vapor Pressure (mm Hg): 1.0 @ 865 C (1589 F)
Vapor Density (Air=1): No information found.
Evaporation Rate: No information found.

SECTION 2 - Fire and Explosion Information

Fire:

Not considered to be a fire hazard.

Explosion:

Not considered to be an explosion hazard.

Fire Extinguishing Media:

Use any means suitable for extinguishing surrounding fire.

Special Information:

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In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

SECTION 3 - Reactivity Data

Stability:

Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products:

When heated to above 801 C (1474 F) it emits toxic fumes of chloride and sodium oxide.

Hazardous Polymerization:

Will not occur.

Incompatibilities:

Lithium, bromide trifluoride.

SECTION 4 - Leak/Spill Disposal Information

Spills: Sweep up and containerize for reclamation or disposal. Vacuuming or wet sweeping may be used to avoid dust dispersal. Disposal: Whatever cannot be saved for reclamation may be delivered to an approved waste disposal facility, or if local ordinances allow, can be dissolved in sufficient amounts of water to meet water quality standards, and flushed down a sewer drain.

Dispose of container and unused contents in accordance with federal, state, and local requirements.

SECTION 5 - Health Hazard Information

A. Exposure/Health Effects

Inhalation:

Inhalation of dust may cause mild irritation to mucous membranes, nose and throat. Symptoms may include coughing, dryness, and sore throat.

Ingestion:

Very large doses can cause vomiting, diarrhea, and prostration. Dehydration and congestion occur in most internal organs. Hypertonic salt solutions can produce violent inflammatory reactions in the gastrointestinal tract.

Skin Contact:

Not expected to be a health hazard.

Eye Contact:

May cause irritation.

Chronic Exposure:

No information found.

Aggravation of Pre-existing Conditions:
No information found.

B. FIRST AID

Inhalation:
Remove to fresh air. Get medical attention for any breathing difficulty.

Ingestion:
If large amounts were swallowed, get medical advice.

Skin Exposure:
Wash exposed area with soap and water. Get medical advice if irritation develops.

Eye Exposure:
Wash thoroughly with running water. Get medical advice if irritation develops.

C. TOXICITY (RTECS, 1986)

Oral rat LD50: 3000 mg/kg. Reproductive effects cited.

SECTION 6 - Occupational Control Measures

Airborne Exposure Limits:
None established.

Ventilation System:
In general, dilution ventilation is a satisfactory health hazard control for this substance. However, if conditions of use create discomfort to the worker, a local exhaust system should be considered.

Personal Respirators: (NIOSH Approved)
For conditions of use where exposure to the dust is apparent, a dust/mist respirator may be worn For emergencies or instances where the exposure levels are not known, use a positive-pressure, air-supplied respirator. WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.

Skin Protection:
Wear protective gloves and clean body-covering clothing.

Eye Protection:
Use chemical safety goggles. Maintain eye wash fountain and quick-drench facilities in work area.

SECTION 7 - Storage and Special Information

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage.

NO NSA

MATERIAL SAFETY DATA SHEET

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Addendum to Material Safety Data Sheet

REGULATORY STATUS

Hazard Categories for SARA Section 311/312 Reporting

Acute	Chronic	Fire	Pressure	Reactive
X				

Product or Components of Product:	SARA EHS Sec. 302 RQ	SARA EHS Sec. 302 TPQ	SARA Sec. 313 Chemicals Name List	SARA Sec. 313 Chemicals Chemical Category	CERCLA Sec.103 RQ lbs	RCRA Sec. 261.3
SODIUM CHLORIDE (7647-14-5)	No	No	No	No	No	No

SARA Section 302 EHS RQ:
Reportable Quantity of Extremely Hazardous Substance, listed at 40 CFR 355.

SARA Section 302 EHS TPQ:
Threshold Planning Quantity of Extremely Hazardous Substance. An asterisk (*) following a Threshold Planning Quantity signifies that if the material is a solid and has a particle size equal to or larger than 100 micrometers, the Threshold Planning Quantity = 10,000 LBS.

SARA Section 313 Chemicals:
Toxic Substances subject to annual release reporting requirements listed at 40 CFR 372.65.

CERLCA Sec. 103:
Comprehensive Environmental Response, Compensation and Liability Act (Superfund) Releases to air, land or water of these hazardous substances which exceed the Reportable Quantity (RQ) must be reported to the National Response Center, (800-424-8802); Listed at 40 CFR 302.4

RCRA:

Resource Conservation and Recovery Act. Commercial chemical product wastes designated as acute hazards or toxic under 40 CFR 261.33.

APPENDIX C:

Emission Permit Table

EMISSION PERMIT TABLE

	Permits for ONY, New York Facility		
Emission	Authorizing Agency	Permit #	Expiration Date
Air	New York State Department of Environmental Conservation	1422 001066 00001 WI 1422 001066 00002 WI 1422 001066 00003 WI	3/18/99 3/18/99 3/18/99
Waste Water	Town of Amherst Sewer Department	Not Required	N/A
Regulated Waste	Environmental Protection Agency	EPA ID # NY0000075754	N/A

09 055